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10/004,873	12/07/2001	Masashi Hakamata	Q67595	7375

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SUGHRUE, MION, ZINN, MACPEAK & SEAS, PLLC
2100 Pennsylvania Avenue, N.W.
Washington, DC 20037-3202

EXAMINER	
FORMAN, BETTY J	
ART UNIT	PAPER NUMBER
1634	

DATE MAILED: 04/14/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/004,873	HAKAMATA, MASASHI	
	Examiner	Art Unit	
	BJ Forman	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *21 January 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-12 and 21-26* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-12 and 21-26* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

FINAL ACTION

Status of the Claims

1. This action is in response to papers filed 21 January 2004 in which claims 1-12 were amended, claims 13-20 were canceled and claims 21-26 were added. All of the amendments have been thoroughly reviewed and entered. The previous objections and rejections in the Office Action dated 22 July 2003 are withdrawn in view of the amendments. All of the arguments have been thoroughly reviewed and are discussed below as they apply to the instant rejections. New grounds for rejection, necessitated by amendment are discussed.

Claims 1-12 and 21-26 are under prosecution.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent

> or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

3. Claims 1, 2 and 10 are rejected under 35 U.S.C. 102(a) and 102(e) as being anticipated by Garner (U.S. Patent No. 6,160,681, issued 12 December 2000).

As discussed above, the claims are indefinite because it is unclear whether an image is analyzed and because it is unclear whether the methods of Claims 2-12 repeat the method of Claim 1 in addition to the reiterated steps. For purposes of examination Claims 1-12 are interpreted as comprising the method steps recited in each claim.

As written the claims are interpreted as being drawn to a method comprising the steps of dropping a dye with a specific binding substance, irradiating the dye, photodetecting the dye, producing template data, producing a template and quantitative analysis. Some claims are further drawn to hybridizing a labeled target to the specific binding substance and irradiating and photodetecting the labeled target. It is noted that the claims do not require that the recited method steps are performed sequentially i.e. in the order they are recited.

Regarding Claim 1, Garner discloses a method comprising the steps of dropping spots (Column 8, lines 53-67) of a specific binding substance onto a substrate to form a plurality of spots (e.g. fluorescently labeled cDNAs, Column 9, lines 33-36), producing a template defining regions of interest (i.e. master grid or dot array, Column 11, lines 1-12) and quantitatively analyzing template (Column 10, lines 16-44).

Regarding Claim 2, Garner discloses the method comprising the steps of dropping spots (Column 8, lines 53-67) of a fluorescent dye together with a specific binding substance onto a substrate to form a plurality of spots (e.g. fluorescently labeled cDNAs, Column 9, lines 33-36), irradiating the spots with a wavelength to simulate the dye, photoelectrically detecting fluorescence emission(Column 8, lines 14-42) producing a template defining regions of interest

(i.e. master grid or dot array, Column 11, lines 1-12) and quantitatively analyzing template (Column 10, lines 16-44).

Regarding Claim 10, Garner discloses the method comprising the steps of dropping spots (Column 8, lines 53-67) of a specific binding substance onto a substrate to form a plurality of spots (e.g. fluorescently labeled cDNAs, Column 9, lines 33-36), irradiating the spots with a light, photoelectrically detecting light from the spots (Column 8, lines 14-42) producing a template defining regions of interest (i.e. master grid or dot array, Column 11, lines 1-12).

Response to Arguments

4. Applicant argues that Garner et al do not delineate a region of interest from their dot array. The argument has been considered but is not found persuasive because "region of interest" is broadly defined in the claim and hence, broadly interpreted to encompass any and all regions on the array e.g. the array is the region of interest. Garner et al specifically define their spots by identifying the spots, first on a control array (Column 11, lines 1-12). As such, the array of spots forming the master grid is a region of interest and is therefore encompassed by the broadly claimed "region of interest".

Applicant further argues that Garner et al do not teach creation of "template data". The argument has been considered but is not found persuasive because Garner et al specifically teach that their spot pattern is data (Column 1, lines 13-14). Garner et al create a template of spots (master grid/dot array) and they teach their spots array is data. Hence, they create template data as instantly claimed.

Applicant's arguments regarding Claims 3-12 are not relevant to the above rejection. Claims 1, 2 and 10 are and were previously rejection under 35 U.S.C. 102(e) over Garner.

5. Claims 1-12 and 21-26 are rejected under 35 U.S.C. 102(b) as being anticipated by Feazel et al (U.S. Patent No. 6,100,030 issued 8 August 2000).

Regarding Claim 1-12, Feazel et al disclose a method of image analysis (Fig. 12) comprising the steps of dropping a dye with a specific binding substance, irradiating the dye, photodetecting the dye, producing template data, producing a template and quantitative analysis and further hybridizing a labeled target to the specific binding substance and irradiating and photodetecting the labeled target (Examples, Column 37, line 46-Column 39, line 25). Feazel et al specifically teach that both the specific binding substance (probe) and target are labeled (Column 23, liens 38-54) wherein the labels include Cy5 and Cy3 (Column 42-59) wherein the hybridization between the probe and target are on a second (i.e. subsequent) substrate (Column 4, lines 31-46) and wherein the irradiation, photodetection and template production is performed serially (Column 4, lines 42-46). Feazel et al further teach the method comprising a second label and second detections step (Column 18, lines 5-16 and Column 25, lines 38-59) wherein the fluorescent dye is contained within a polymer e.g. attached to the polynucleotide and/or coupled to polystyrene beads (Column 30, line 7-Column 32, line 13).

Regarding Claim 21, Feazel et al disclose the method wherein the quantitative image analysis (Column 21, lines 22-47) includes reading image data in a two-dimensional map i.e. array (Column 50, line 21-Column 51, line 60).

Regarding Claim 22, Feazel et al disclose the method wherein the reading includes reading size and position of the fluorescently detected emission i.e. the position is read and related to the sample of known size (Column 51, line 20-Column 53, line 3 and Claim 14).

Regarding Claim 23, Feazel et al disclose the method wherein the image data is compared to the template to determine regions of interest i.e. sample data is compared to normalized template to identify regions of interest (Column 21, lines 21-47).

Regarding Claim 24, Feazel et al disclose the method wherein regions of interest are superimposed with image data (Column 51, line 1-60).

Regarding Claim 25, Feazel et al disclose the method wherein the fluorescent dye is contained within a polymer e.g. attached to the polynucleotide and/or coupled to polystyrene beads (Column 30, line 7-Column 32, line 13). The claim is drawn to a polymer of a high viscosity. The term "high" is a relative term. However, the claim does not describe a relationship within which the polymer viscosity is high. For example, the claim does not require that the polymer viscosity be high relative to water. It is noted that any viscosity is high when compared to some other less viscous composition. Because the claim does not describe or define the claimed "high viscosity" the claim is given its broadest reasonable interpretation. As such, the polymer of Feazel et al is of high viscosity when compared to some other less viscous composition.

Regarding Claim 26, Feazel et al disclose the method further comprising setting a region of interest (e.g. corner dot) and performing quantative image analysis base on the region of interest (Column 50, line 20-Column 53, line 3).

Response to Arguments

6. Applicant argues that Feazel et al do not teach creation of "template data" for defining regions of interest from their dot array. The argument has been considered but is not found persuasive because "region of interest" is broadly defined in the claim and hence, broadly interpreted to encompass any and all regions on the array e.g. the array is the region of interest. Feazel et al specifically define their spots by normalization of signal from the spots wherein the normalization provides the claimed "template data" (Column 21, lines 22-47).

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

8. Claims 3-9 and 11-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Garner (U.S. Patent No. 6,160,681, issued 12 December 2000) in view of Feazel et al (U.S. Patent No. 6,100,030 issued 8 August 2000).

Regarding Claims 3-9 and 11-12, Garner discloses various combination so the method comprising the steps of dropping spots (Column 8, lines 53-67) of a specific binding substance onto a substrate to form a plurality of spots (e.g. cDNAs, Column 9, lines 33-36), hybridizing a substance derived from an organism with the binding substance, irradiating the spots with a wavelength to simulate the dye, photoelectrically detecting light form the spots (Column 8, lines 14-42) producing a template defining regions of interest (i.e. master grid or dot array, Column 11, lines 1-12) irradiating the spots with a stimulating ray, photoelectrically detecting emission, defining regions to be quantified (i.e. subsequent array) and quantitatively analyzing template (Column 10, lines 16-44 and Column 11, lines 1-12). Furthermore, they teach the labels are comprised of any of the numerous fluorochromes and dyes well known labels e.g. energy transfer which clearly suggests that both the specific binding substance and target are labeled (Column 7, line 42-Column 8, line 3). But Garner does not specifically teach that the specific binding substance and the target are both labeled fluorescent dye.

However, Feazel et al teach a similar method wherein both the specific binding substance and the target are labeled with a fluorescent dye. It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to apply the probe and

target labeling of Feazel et al to the target quantification of Garner. The motivation to do so comes first from Garner who suggest that both are labeled (Column 7, lines 42-46) and second from Feazel et al wherein they teach that labeling both target and probe provides for rapid and specific detection (Column 23, lines 38-53).

Garner teaches that the label comprises any one of numerous fluorescent dyes known in the art e.g. Cy3,Cy5, Fluor X (Column 7, line 42-Column 8, line 3). The specification repeatedly teaches the fluorescent dyes comprise Cy3,Cy5, Fluor X (e.g. pages 68-69) but the specification does not teach or define other dyes which are fluorescent dyes contained in a polymer comprising the steps of causing the polymer to contain the specific binding substance. While limitations from the specification are not read into the claims, Claims 6-8 are interpreted in light of the specification wherein the dyes are selected from Cy3,Cy5, Fluor X. As such, Garner teaches the dye as claimed (Column 7, line 42-Column 8, line 3).

Response to Arguments

9. Applicant relies on the arguments discussed above regarding Garner et al. The arguments have been considered but are not found persuasive as discussed above.

10. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after

the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Conclusion

11. No claim is allowed.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to BJ Forman whose telephone number is (571) 272-0741. The examiner can normally be reached on 6:00 TO 3:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on (571) 272-0782. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

BJ Forman, Ph.D.
Primary Examiner
Art Unit: 1634
April 12, 2004